EPA/OPP MICROBIOLOGY LABORATORY
ESC, Ft. Meade, MD

Standard Operating Procedure
for
VITEK: Quality Control Procedures

SOP Number: QC-17-03

Date Revised: 09-28-05

Initiated By: _____Date: ___/___/___

Print Name:_____

Technical Review: _____ Date: ___/___/___

Print Name:_____
Technical Staff

QA Review: _____ Date: ___/___/___

Print Name:_____
QA Officer

Approved By: _____ Date: ___/___/___

Print Name:_____
Branch Chief

Effective Date: ___/___/___

Controlled Copy No.: _____

Withdrawn By: _____ Date: ___/___/___

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1.0 SCOPE AND APPLICATION:

1.1 This protocol describes the method for verifying the performance of the Vitek Gram-Positive Identification Card (GPI), *Bacillus* Biochemical Card (B), and the Gram-Negative Identification+ (GNI+) Card.

2.0 DEFINITIONS:

2.1 ATCC = American Type Culture Collection

3.0 HEALTH AND SAFETY:

3.1 Laboratory personnel should follow biosafety procedures appropriate for the organism being confirmed as outlined in SOP MB-01, Biosafety in the Laboratory.

4.0 CAUTIONS:

4.1 The QC procedure for all Vitek QC Organisms can take up to three weeks to complete due to the fastidious nature of some of the organisms. Repeat procedures for some organisms may be necessary. The analyst should plan this QC activity accordingly in order to complete it in an appropriate time frame.

5.0 INTERFERENCES:

5.1 Do not use Vitek cards beyond expiration date because it may result in erroneous readings.

5.2 Improper maintenance of stock cultures, subculturing, and filling of Vitek cards may result in inconsistent or erroneous biopatterns.

6.0 PERSONNEL QUALIFICATIONS:

6.1 Personnel are required to be knowledgeable of the procedures in this SOP. Documentation of training and familiarization with this SOP can be found in the training file for each employee.

7.0 SPECIAL APPARATUS AND MATERIALS:

7.1 Vitek 32 System for the automated identification of microorganisms.

7.2 Vitek 32 Identification cards (GPI, B, and GNI+).

7.3 Quality control organisms listed in Section 10.

8.0 INSTRUMENT OR METHOD CALIBRATION:

8.1 Factory Calibrations: Prior to shipment, the Vitek 32 Instrument met all acceptance test procedures stipulated by bioMerieux. The Field Service Engineer has performed a verification of the bioMerieux Vitek, Inc. factory calibration as a part of the installation procedure of this instrument. The instrument test analysis outlined on the installation checklist has been performed and has met the instrument engineering specifications as indicated on the Customer Calibration Verification certificate (see 16.2).

8.2 Internal monitoring of the Vitek reader/incubator module.

8.2.1 The Vitek reader/incubator module houses the card handling and scanning mechanism as well as the heater that maintains the cards at the required incubation temperature. The trays that hold the cards are mounted to a carousel that rotates once every 15 minutes to position the cards for data scanning and identification. A thermistor is located in the center of the carousel shaft and positioned to monitor any change of temperature in the carousel stack. A heater and fan on top of the carousel maintains the temperature at 35°C.

The incubation temperature is verified during the Vitek system test. Temperature deviations of ±2°C generate error messages at the data terminal module such as, "Reader Temperature High," or "Reader Temperature Low." The process cycle is aborted if the temperature varies ±5°C from the set temperature for more than one hour. The thermistor assembly in the Vitek Reader is used as an absolute reference in the Vitek System. Each thermistor assembly is tested at the Vitek manufacturing facility to Vitek's test specifications, using equipment calibrated to the National Bureau of Standards. In a final test, the Reader and the other Vitek modules are functionally tested as a system.

8.2.2 The optical system in the Vitek consists of Light Emitting Diodes (LED's) which generate light at a precise wavelength and photo transistors which detect that light. The LED array is physically

aligned in a plane 180 degrees with respect to the photo transistors. The LED/photo transistor array is formatted physically to the VITEK Card in a figure eight design for the identification segment of the card and in a row of five for the growth wells. The specifications of the LED's and the photo transistors, along with their corresponding tolerance, result in a transfer function which relates the LED excitation currents to the photo transistor detection current within a tolerance. That relationship is verified in a calibration algorithm which is coded into the firmware (software) of every Reader. If any part of that transfer function is out of tolerance, it is indicated with a "calibration failure" message; and processing will not resume until the calibration tests are completed successfully. Every LED/photo transistor pair is calibrated by this process, and this occurs during the production process as well as during actual operation of the Reader in the field. Calibration is completed before reading every tray.

In addition to the optical testing, a series of test protocols are performed on the Reader/Incubator system prior to shipment. The card handling system, carousel sensor, optical tray sensor, cars stop and horizontal in/out stops are verified and/or adjusted for optimal performance. Output voltages are verified on pins and connectors for the Intelligent Reader Board and Reader/Incubator Boards, and system is readied for a '"burn-in" test. "Burn-in" consists of loading the instrument with non-inoculated but otherwise functional cards and then processing them for four hours. All messages are checked for correctness and the system is then secured for packaging and shipment.

8.2.3 A performance check of the VITEK unit will be performed on an annual basis by a trained bioMerieux technician. All service and recertification documents will be maintained in the VITEK Maintenance and Certification Records Book.

9.0 SAMPLE HANDLING AND STORAGE:

9.1 Vitek Cards (GPI, GNI and BAC) must be stored between 2-5°C. If the temperature of the cards has been compromised, the cards will be discarded.

10.0 PROCEDURE AND ANALYSIS:

10.1 Quality control procedures consist of performing standard VITEK analyses using a specified set of known microbes based on recommendations from bioMerieux) in conjunction with the appropriate card types. The QC will be performed on a annual basis. QC organisms and associated card types are listed in Table 1.

10.2 Lyophilized cultures will be purchased from the ATCC and will be stored according to the ATCC recommendations (in trypticase soy broth with 20% glycerol at -70°C). Cultures are propagated for storage according to the Product Information Sheets supplied by ATCC. An expiration date will be established for all cultures at the time of freezing.

10.3 Stored cultures will be initiated for VITEK analysis according to the VITEK Pinsert instructions outlined in the VITEK Pinsert Folder (see VITEK Pinsert for each organism).

10.4 For VITEK analysis, organisms are assigned a 7 digit identification number (format: 000000-0). The first six digits are the Reference Number for the organism as listed in Table 1. The seventh digit is assigned by VITEK automatically and is derived from the VITEK card lot being used. The six digit number is entered directly onto the VITEK card and will appear later on the VITEK QC Deviation Report. Follow the instructions for labeling cards outlined in the VITEK Pinsert Folder. Identification numbers are recorded on the VITEK Quality Control Log in the VITEK QC Log Book. Quality Control organism tracking and Deviation Reports are maintained in the VITEK Quality Control Record Log Book.

10.5 Following analysis, the VITEK unit will automatically print a VITEK QC Exceptions Report; a report which displays any deviations of “expected” reactions versus those “observed” during the analysis (see 16.3).

10.6 Repeat the assay if an exception report is generated.

Table 1. Quality Control Organisms for VITEK 32 Automated Identification System

Organism	ATCC #	Card	Reference Number

Bacillus licheniformis	12759	B	600101
Bacillus sphaericus	4525	B	600102
Proteus mirabilis	7002	GNI+	900101
Providencia alcalifaciens	51902	GNI+	900102
Klebsiella pneumoniae	13883	GNI+	900103
Plesiomonas shigelloides	51903	GNI+	900104
Bordetella bronchiseptica	10580	GNI+	900105
Serratia liquefaciens	27592	GNI+	900106
Leclercia adecarboxylata	23216	GNI+	900107
Burkholderia cepacia	25608	GNI+	900108
Enterococcus durans	6056	GPI	800101
Streptococcus equi	9528	GPI	800102
Streptococcus bovis	9809	GPI	800103
Erysipelothrix rhusiopathiae	19414	GPI	800104
Streptococcus pyogenes	19615	GPI	800105
Enterococcus faecalis	29212	GPI	800106
Staphylococcus xylosus	29971	GPI	800107

11.0 DATA ANALYSIS/CALCULATIONS: None

12.0 DATA MANAGEMENT/RECORDS MANAGEMENT:

12.1 Data will be recorded promptly, legibly, and in indelible ink. Information on Quality Control will be recorded on the Quality Control Record Log Sheet (see 16.1). Quality Control organism tracking forms will be maintained in the VITEK Quality Control Record Book. Completed forms and reports are archived in notebooks kept in secured file cabinets in file room D217. Only authorized personnel have access to the secured files. Archived data is subject to OPP's official retention schedule contained on SOP ADM-03, Records and Archives.

13.0 QUALITY CONTROL:

13.1 All information regarding the organism's used for the QC procedure of Vitek are documented on the appropriate Organism Culture Tracking Forms.

14.0 NONCONFORMANCE AND CORRECTIVE ACTION:

14.1 A VITEK QC Exception Report is generated if an actual value differs from an expected value. If the QC Exception Report is generated, the QC procedure should be repeated. Strict adherence to given parameters for that organism should be followed, specifically the instructions for maintaining the organism prior to inoculating the VITEK card (i.e., passing the organism the indicated number of times on the specified medium, the proper age organism, the proper optical density for that card, etc.). If the same results are returned on the QC Exception Report, a bioMerieux technician should be notified and maintenance scheduled. The machine should not be used for confirmation until it is serviced and recertified.

15.0 REFERENCES:

15.1 bioMerieux VITEK, Inc. 1997. Industrial Automated Microbiology Systems Summary, Part Number 512312-2, REV 0597.

15.2 bioMerieux VITEK, Inc. Aug. 26, 1998. Pinsert, VITEK Software Programs and Data, VTK-R06.01

16.0 FORMS AND DATA SHEETS:

16.1 Quality Control Record Log Sheets

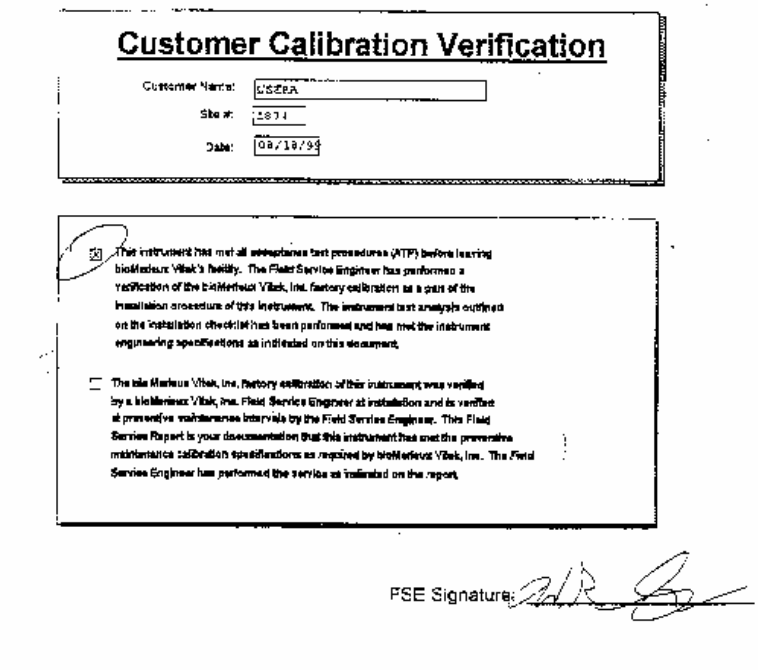
16.2 Customer Calibration Verification Certificate

16.3 Sample QC Deviation Report

Vitek Quality Control Record Log Sheet
OPP Microbiology Laboratory

QUALITY CONTROL RECORD LOG					
Date/Init.	Reference No.	Card*	Card Lot	Organism	Miscellaneous Test Results+

* Enter Vitek card type (B, GNI+, or GPI for Bacillus card, Gram Negative Identification, or Gram Positive Identification respectively)
\+ Miscellaneous results include catalase test for Bacillus species and Staphylococcus, coagulase test for Staphylococcus species, and oxidase test for Gram negative rods.



Customer Calibration Verification

Customer Name: USEPA

Site #: 2874

Date: 08/18/99

☒ This instrument has met all acceptance test procedures (ATP) before leaving bioMerieux Vitek's facility. The Field Service Engineer has performed a verification of the bioMerieux Vitek, Inc. factory calibration as a part of the installation procedure of this instrument. The instrument test analysis outlined on the installation checklist has been performed and has met the instrument engineering specifications as indicated on this document.

☐ The bioMerieux Vitek, Inc. factory calibration of this instrument was verified by a bioMerieux Vitek, Inc. Field Service Engineer at installation and at preventive maintenance intervals by the Field Service Engineer. This Field Service Report is your documentation that this instrument has met the preventive maintenance calibration specifications as required by bioMerieux Vitek, Inc. The Field Service Engineer has performed the service as indicated on the report.

FSE Signature:

Customer Calibration Verification Certificate
US EPA/OPP/Microbiology Laboratory

Sample QC Deviation Report

US EPA/OPP/Microbiology Laboratory

Date: 03/16/2000 [illegible]
[illegible]

bioMerieux Vitek
Vitek QC Exception Report

Test Type: Bacil Card Lot: [illegible] Expiration: [illegible]/07/2000
Test Date: 03/16/2000 Technologist:
Expected Organism ID: ATCC 12759 Bacillus licheniformis
Actual Organism ID: Bacillus licheniformis

Biochem [illegible]
Expected [illegible]
Actual [illegible]

Deviations: NIL